



# Duplex Guided Dialysis Access Interventions can be Performed Safely in the Office Setting: Techniques and Early Results

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## KEYWORDS

Dialysis;  
Angioplasty;  
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**Abstract** *Objective:* To determine the utility of duplex guided angioplasty for hemodialysis access maturation and maintenance.

*Design/Materials/Methods:* Between January 2008 and June 2009, 223 office-based duplex-guided hemodialysis access angioplasty procedures were performed in 125 patients. Two hundred eight of the accesses were autogenous. The most common indication for intervention was maturation failure (104 cases). Other indications included pulsatility, low access flow, decreased flow and infiltration. Procedures were performed in the office using topical and local anesthesia. Volume flow (VF) was recorded prior to introducer insertion (baseline) and post intervention.

*Results:* Technical success was achieved in 219 cases (98.2%). Minor complications occurred in 21 cases (9.4%). Immature autogenous AV accesses had a median baseline VF of 210 mL/min. Median final VF for these autogenous AV accesses was 485 mL/min. The VF increased by 131%. Dysfunctional autogenous AV accesses and nonautogenous AV accesses had a median baseline VF of 472 mL/min. Median final VF was 950 mL/min. The VF increased by 101%.

*Conclusions:* Duplex guided dialysis access angioplasty can be performed safely and effectively in the office setting. It offers the advantage of treating the patient without radiation or contrast as well as the assessment of the hemodynamic effects of intervention.

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## Introduction

Endovascular intervention for immature or malfunctioning AV access has traditionally been performed using techniques dependent upon fluoroscopic guidance. These techniques expose the patient to the risks associated with exposure to iodinated contrast and ionizing radiation.<sup>1–3</sup> Sedation has also been routinely administered during these procedures. Sedation also carries risks, particularly in patients with renal failure as a consequence of enhanced drug sensitivity, co-morbidities and concurrent medication use.<sup>4</sup> Additional drawbacks of the traditional approach include exposure of personnel to radiation and the high costs associated with fluoroscopic imaging hardware, contrast and personnel required for the monitoring of patients who have received IV sedation.<sup>5–7</sup>

To avoid these hazards, techniques have been developed for hemodialysis access intervention that utilize duplex ultrasound guidance.<sup>1,6–17</sup> Although first reported by Wittenberg in 1996,<sup>17</sup> there has been a recent increase in reports of ultrasound guided dialysis intervention. The Maimonides group has published several favorable reports of Duplex-guided hemodialysis access intervention in both failing and non-maturing accesses.<sup>1,6,11,12</sup> They have also shown that these procedures can be safely and successfully performed in the office setting.<sup>1</sup> Furthermore, ultrasound guided access intervention has been shown to offer economic advantages for the medical system as well as the practitioner.<sup>1,18</sup> As mentioned previously, the clinical advantages of duplex-guided intervention include avoidance of the risks of iodinated contrast, ionizing radiation and sedation. There are also significant technical advantages including the ability to directly visualize puncture sites, stenoses, thrombus, spasm and extravascular flow in real-time.<sup>16</sup>

By using duplex one is also able to directly measure the diameter of treated vessels, which facilitates the accurate sizing of balloons and stents. The ability to measure diameter, flow velocity and volume flow also provides the opportunity to objectively and quantitatively assess the need for and the results of intervention.<sup>19</sup>

Further advantages include a strong patient and physician preference for the convenience and efficiency of the office environment as compared to the hospital. In light of the favorable experience reported, we began performing office-based duplex-guided access intervention in January of 2008. In this report we describe these techniques and present our early results.

## Materials and Methods

### Demographics

During the 17-month period of January 2008 through June 2009, 223 consecutive office-based duplex-guided hemodialysis access interventions were performed in 125 patients by a single vascular surgeon (DF) in a practice with a strong focus on the creation and maintenance on hemodialysis access (Table 1). There were 68 males and 57 females. Mean age was 65.5 years; range 29–89 years. The anatomic distribution of the treated accesses was the forearm in 67%

**Table 1** Patient characteristics.

Variable	n
Interventions, No.	223
Patient, No.	125
Sex M/F, No.	68/57
Age, years	65.5 (29–89)
Access location	
Forearm	67%
Arm	33%
Access type	
Autogenous AV access	208
Nonautogenous AV access	15

and the upper arm in 33%. The majority of treated accesses were autogenous AV accesses (AAVA) (208). Fifteen were nonautogenous (NAAVA).

### Indications

The most common indication for intervention was maturation failure, which occurred in 104 cases (Table 2). A diagnosis of maturation failure was made using both clinical and duplex criteria. Duplex criteria include AAVA diameter less than 6 mm and access flow less than 600 mL/min. Clinical criteria included the inability to achieve prescribed dialysis flow rates and difficulty with cannulation. Other indications included pulsatility (29), low access flow (28), decreased access flow (23), infiltration (13), aneurysmal degeneration (11), bleeding (9), pseudoaneurysmal degeneration (6), elevated venous pressures (5), difficult cannulation (3), pain (3), ulceration (1), decreased clearance (1), swelling (1) and decreased arterial pressures (1). More than one indication for intervention was often present in an individual patient. Hemodynamically significant stenoses were identified and characterized by the presence of B-mode diameter reduction, color bruit and peak systolic velocity elevation  $>2$ .<sup>1,7,20–22</sup>

**Table 2** Indications for intervention.<sup>a</sup>

Variable	n
Maturation failure	104
Pulsatility	29
Low access flow	28
Decreased access flow	23
Infiltration	13
Aneurysmal degeneration	11
Bleeding	9
Pseudoaneurysmal degeneration	6
Elevated venous pressures	5
Difficult cannulation	3
Pain	3
Ulceration	1
Recirculation	1
Swelling	1
Decreased arterial pressures	1

<sup>a</sup> More than one indication for intervention was often present in an individual patient.

## Exclusion criteria

Patients were not considered appropriate candidates for office-based duplex-guided intervention in a small number of defined clinical circumstances. When such a circumstance did occur, the patient underwent conventional treatment in a hospital setting. Exclusion criteria included both anatomic and non-anatomic characteristics.

An important anatomic exclusion criterion was the suspicion of clinically relevant central vein pathology. Central vein pathology was suspected in patients with a clinical presentation of arm swelling and/or a history of clinically significant central vein pathology or abnormal duplex findings. Duplex findings suggestive of central vein abnormalities include those directly visualized or indirectly inferred by duplex waveform analysis. A finding of a non-pulsatile central vein waveform ipsilateral to the access suggested a hemodynamically significant stenosis or occlusion central to the area of anastomosis.<sup>23–27</sup> This was an uncommon occurrence in our series perhaps as a result of our practice to routinely assess the central veins in patients perceived to be at risk for occult central vein pathology prior to access creation. The low incidence of central vein pathology in our series is consistent with the observations of Kanterman who found that in a large series of vascular graft access malfunction, 93% of stenotic lesions are located between the arterial anastomosis and the axillary vein.<sup>28</sup>

Non-anatomic characteristics of patients excluded from in office treatment include those with a strong preference for treatment in a hospital setting or those requiring sedation. Again, these were uncommon events in our series.

## Interventions

The types of intervention performed under duplex guidance included maturation angioplasty and maintenance angioplasty. Maturation angioplasty was performed in 115 cases. Maintenance angioplasty was performed in 108 cases.

## Technique

All procedures were performed in a freestanding office procedure room. Room setup for the procedure is illustrated in Figs. 1 and 2. Both the surgeon and vascular technologist scrubbed for the procedure. A non-scrubbed circulator was present. Occasionally an assistant scrubbed in as well. Patients were instructed to apply a topical anesthetic cream (2.5% lidocaine/2.5% prilocaine) with an occlusive dressing over the access site two to 3 h prior to the procedure. After informed consent was obtained the extremity was scrubbed with chlorhexidine and draped in the usual sterile manner. Local infiltration at introducer and angioplasty sites was performed with an equal parts mixture of 2% Lidocaine and 1% Bupivacaine. A small quantity of sodium bicarbonate solution was added to the mixture to reduce acidity. No intravenous sedation was administered.

Image guidance for the procedure was obtained using the Zonare z.one ultra Ultrasound System (Zonare Medical Systems, San Francisco, California, USA). Both the keyboard



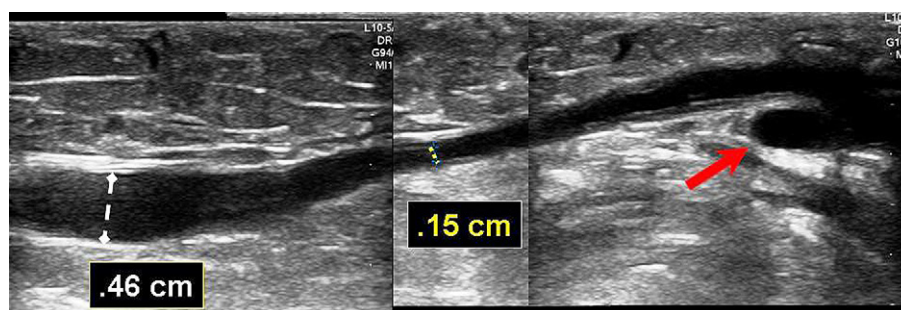
**Figure 1** Procedure room setup for duplex guided AV access intervention. The patient's right arm is seen in the middle of the figure. The duplex scanner is in the background.

and probe (L10-5 Linear array transducer) were covered with sterile plastic drapes (Civco Medical Solutions, Kalona, Iowa, USA). After baseline measurements were recorded (volume flow, vessel diameter and flow velocity), access was obtained using a 5 French micropuncture set (Merit Medical Systems, South Jordan, Utah, USA). Both antegrade and retrograde approaches were utilized depending upon the anatomical location of the stenosis.

Angioplasty balloon size was determined by measuring the vessel diameter adjacent to the stenotic segment and oversizing by 1–1.5 mm. Once the angioplasty balloon had been selected, the micropuncture catheter was exchanged for an introducer sheath and 3000 units of heparin were administered through the sheath. Additional 1000 unit doses were administered after 45 min when necessary. 4 French through 7 French diameter introducer sheaths were used (Terumo Medical Corporation, Somerset, New Jersey, USA).

A guidewire (.035 or .018 mm) was then advanced through the stenotic area and positioned beyond the stenosis in such a manner as to maintain good endovascular control of the area to be treated. All these maneuvers were performed under direct, continuous duplex ultrasound guidance so as to avoid inadvertent wire passage into tributaries or vessel wall trauma. At this point, ultrasound guided local anesthetic infiltration at the angioplasty site was performed. Care was taken to administer the perivenous anesthetic prior to balloon insertion so as to avoid the possibility of angioplasty balloon puncture with the anesthetic needle.

Angioplasty was then performed with either low profile, standard-pressure, high-pressure or cutting balloons as indicated by stenosis characteristics and response to angioplasty. Angioplasty balloon diameters ranged between 2 mm and 12 mm. The diameter of balloon most commonly used was 6 mm (Table 3). The balloons used in this study were Ultraverse, Vaccess and Conquest (CR Bard, Murray Hill, New Jersey, USA). Cutting balloons (Boston Scientific, Natick, Massachusetts, USA) were required for resistant stenoses in 3 cases. Once full profile was achieved, the inflation pressure was typically brought several atmospheres higher and then maintained for a period of approximately



**Figure 2** Composite duplex scan of a non-maturing autogenous high origin radial artery-basilic vein transposition. The arrow indicates the inflow radial artery. There is a long area of arterial end stenosis which measures .15 cm in diameter.

60 s. Duplex images from a representative case are shown in Figs. 3–5.

Post angioplasty duplex assessment was then performed. This included measurement of diameter; velocity and volume flow as well as assessment for complications such as rupture, thrombosis or spasm. After a final result had been achieved, 4-0 polypropylene sutures were placed at the introducer sites and the introducers were removed. Partially occlusive pressure was held for approximately 3 min after which the access sites were interrogated for hemostasis. An additional period of compression was performed if necessary. Once hemostasis had been demonstrated, final measurements of diameter, velocity and volume flow were obtained. A dressing was then placed, vital signs were checked and the patient was discharged. Procedure duration averaged 55 min with a range of 15–169 min.

A determination of technical success was made at the time of the procedure. This determination was made upon consideration of a number of quantifiable factors such as changes in vessel diameter, reduction in flow velocity ratio to less than 2 and volume flow. The determination also took into account subjective phenomenon such as vasospasm at angioplasty and introducer sites which can transiently blunt changes in the quantitative endpoints.

For the purpose of this study only volume flow measurements are reported. Volume flow measurements were made in a non-tortuous segment of the access that demonstrated laminar color flow. Volume flow was

recorded prior to introducer insertion (baseline) and post intervention. Final volume flow was also recorded post introducer removal. An effort was made to record volume flow in the same anatomic site to minimize measurement variability related to anatomical factors.

Statistical analysis was performed using SigmaStat, Version 3.5. The statistical significance of differences in volume flow measurements pre and post intervention was assessed using the Paired *t*-test. The data distribution was first evaluated with the normality test and the data was found to be non-parametric in all comparisons. Because of this the Wilcoxon Signed Rank Test was applied and median values were reported.

## Results

### Technical success

Technical success was achieved in 219 cases (98.2%). Technical failure was experienced in 4 cases (1.79%). These failures occurred in 4 maintenance angioplasty cases. There were no technical failures in the maturation series. Technical failure was the result of an inability to cross an occluded anastomosis or outflow segment in two cases. The causes of technical failure in the two other cases were recoiling stenosis and resistant stenosis. These were addressed with surgical repair and cutting balloon respectively.

Stents were placed in 5 cases. Four of the stents were covered, 1 stent was a bare metal stent. The most common indication for stent placement was pseudoaneurysm formation (2). Other indications for stent placement were vein rupture (2) and elastic recoil (1). Arterial angioplasty (in addition to venous or graft angioplasty) was performed in 16 cases. Trans-radial access was not utilized in this series.

### Complications

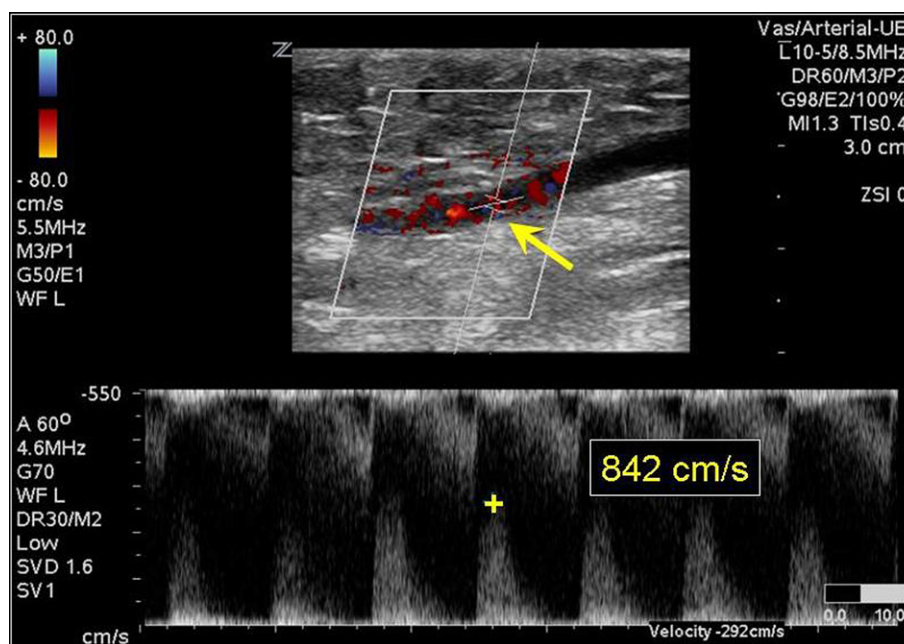
Minor complications occurred in 17 cases (7.6%). There were 2 major complications (.89%). Access-site related complications included small introducer site hematomas in 2 cases and the formation of small introducer site pseudoaneurysms in 4 cases. These findings were visualized on ultrasound but in general were not otherwise clinically apparent. When visualized, a brief period of manual

**Table 3** Frequency of angioplasty balloon use.

Balloon diameter (mm)	First balloon, No.	Second balloon, No. <sup>a</sup>
2	—	1
3	1	6
4	14	4
5	44	6
6	65	6
7	42	3
8	23	4
9	16	2
10	9	—
12	1	—

<sup>a</sup> When a second balloon was required.



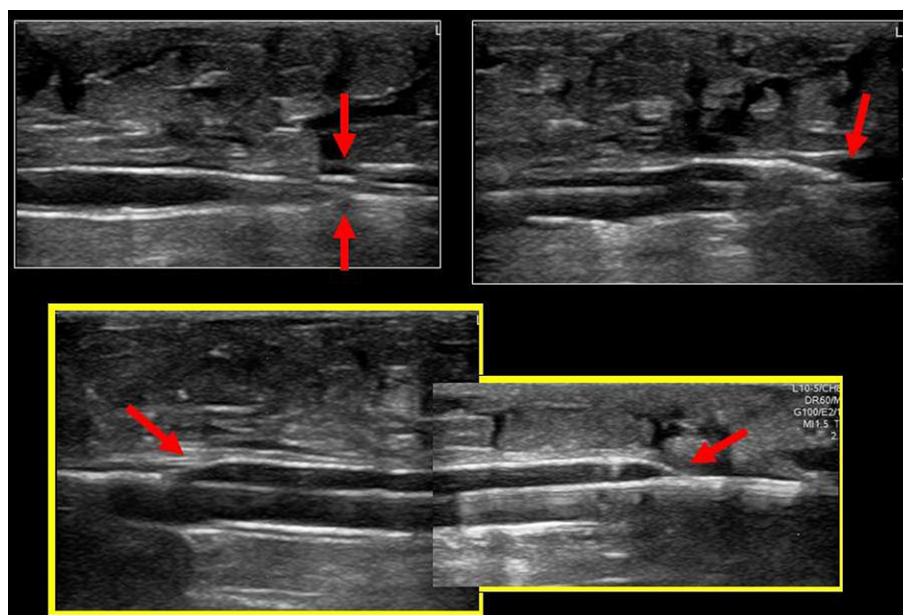


**Figure 3** Baseline duplex showing mosaic color bruit and high flow velocity (842 cm/s) with aliasing.

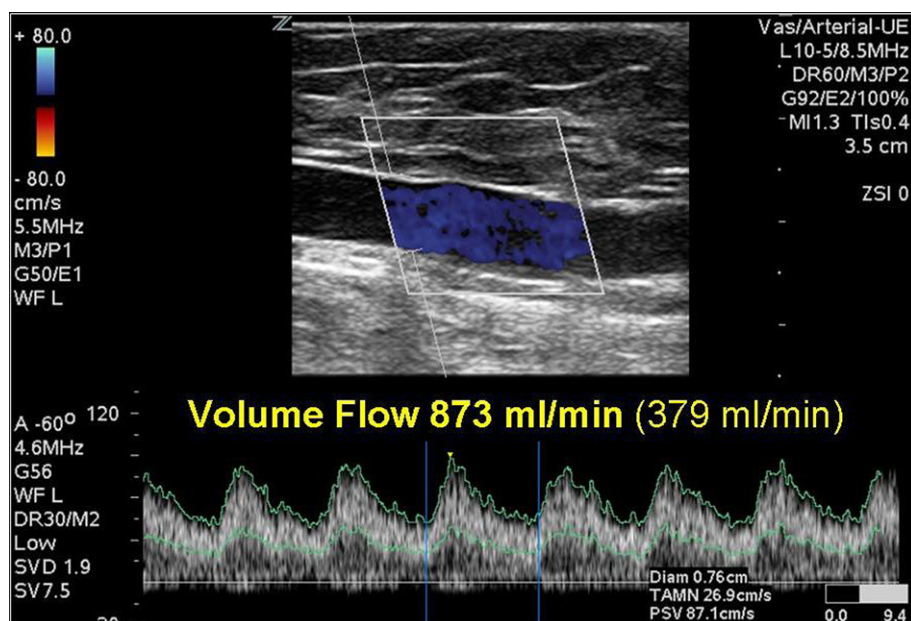
compression was performed. Complete resolution of these access-site related complications was achieved in all cases.

Intra-luminal thrombus development was seen in 8 cases. This was seen at both angioplasty and introducer sites. When the thrombus was occlusive or appeared to present a potentially significant obstruction to flow, additional heparin was given and maceration thrombectomy was performed. Thrombectomy was successful in all cases.

Angioplasty site rupture was seen in 3 cases. Initial treatment included balloon re-inflation and external compression. Covered stent placement (Fluency, CR Bard) was performed in 2 of the cases of rupture. Control of rupture was achieved in all cases. Small angioplasty site pseudoaneurysms developed in 2 cases. One was treated with compression. The second was observed and remained stable.



**Figure 4** B-mode images depicting angioplasty balloon inflation. Top left image shows a waist in the balloon at the site of maximal stenosis. Top right image shows full profile at the stenosis site. Arrow points to the transition point between balloon and guidewire. Bottom image taken with balloon at full profile. Arrows indicate the central and peripheral ends of the balloon. The bright line extending across the entire image represents a Bentsen wire.



**Figure 5** Duplex showing markedly increased volume flow following angioplasty of arterial end stenosis. Volume flow increased from 379 to 873 mL/min.

## Volume flow

Volume flow (VF) was measured pre and post intervention. A complete set of both pre and post intervention VF measurements were available for analysis in 205 of the 223 procedures (92%). Average and median VF for each type of intervention were calculated and pre and post intervention volume flows were compared. VF was found to increase significantly across all treatment categories (Table 4). As the data distribution was found to be non-parametric, the median VF rather than the average VF was used for determination of statistical significance.

For all interventions combined, the median baseline VF was 340 mL/min. The median final VF was 663 mL/min. The VF increased by 95% post intervention ( $P < 0.001$ ).

The immature AAVA's undergoing maturation angioplasty had a median baseline VF of 210 mL/min. Median final VF for these AAVA's was 485 mL/min. The VF increased by 131% after maturation angioplasty ( $P < 0.001$ ).

Dysfunctional AAVA's and NAAVA's undergoing maintenance angioplasty had a median baseline VF of 472 mL/min. Median final VF was 950 mL/min. The VF increased by 101% after maintenance angioplasty ( $P < 0.001$ ).

Looking exclusively at the technically successful maintenance procedures, the median baseline VF was 451 mL/min. Median final VF increased to 955 mL/min. The VF increased by 84% post intervention ( $P < 0.001$ ).

## Discussion

Our study clearly demonstrates that office-based duplex-guided intervention is a safe and effective treatment for immature and failing AV access. The principal measure of therapeutic success was a significant increase in duplex derived flow volume.

Duplex derived access volume flow (DAVQ) has been reported by Ascher to be a good predictor of clinical success following endovascular repair of failing or immature access.<sup>29</sup> He found that DAVQ for functioning AAVA's averaged 1199 mL/min. The DAVQ in AAVA's that underwent intervention and went on to become functional for dialysis for at least 6 months was at least 867 mL/min. In our series, the mean and median final volume flow for all interventions was 820 and 663 mL/min. This is within range of the level reported by Ascher so it is reasonable to infer that the clinical outcomes in our series would be comparable.

Looking specifically at the accesses in our series that underwent maintenance angioplasty, the mean and median final VF were 1146 and 950 mL/min. This compares favorably to the number reported by Ascher (1199 mL/min) so it is reasonable to infer that the clinical outcomes of our maintenance procedures would be excellent as well.

At first glance, the results of the maturation cases appear not be as favorable as those of maintenance cases. The mean and median final VF for the maturation cases were 522 and 485 mL/min. While these indicate a substantial increase in VF from baseline (93 and 131%), these values are below the threshold of 867 mL/min reported by Ascher. It is important to remember, however, that the final VF for maturation cases in our series reflects AAVA's that were in various stages of maturation and is not the final volume flow achieved after a complete series of maturation angioplasty sessions for each AAVA. It therefore likely that these aggregate numbers do not reflect values that would be seen following a complete series of maturation. It would be instructive to perform a separate analysis of the patients that had undergone a complete series of maturation.

When comparing the results of our VF data to those of other studies, it is important to note that volume flow measurements obtained immediately after angioplasty and

**Table 4** Volume flow measurements (VF).

Procedure type	n	Mean	SD <sup>a</sup>	Range	Median	25% IQR <sup>b</sup>	75% IQR	P <sup>c</sup>
Maintenance + maturation (All cases)								
VF Pre (mL/min)	205	447	421	12–3265	340	168	556	
VF Post (mL/min)	205	820	600	116–4475	663	444	1001	
% Increase in VF		84%			95%			<.001
Maintenance PTA (All cases)								
VF Pre (mL/min)	98	639	506	110–3265	472	300	806	
VF Post (mL/min)	98	1146	684	200–4475	950	721	1404	
% Increase in VF		79%			101%			<.001
Maintenance PTA (Successful cases)								
VF Pre (mL/min)	94	616	437	110–2537	451	300	806	
VF Post (mL/min)	94	1143	652	286–4475	955	727	1404	
% Increase in VF		85%			112%			<.001
Maturation PTA (All)								
VF Pre (mL/min)	107	271	201	12–1030	210	108	397	
VF Post (mL/min)	107	522	272	116–1410	485	292	658	
% Increase in VF		93%			131%			<.001

<sup>a</sup> SD, Standard deviation.<sup>b</sup> IQR, Inter-quartile ratio.<sup>c</sup> Wilcoxon signed rank test.

introducer removal (as reported in this series) will display a tendency to underestimate the effectiveness of angioplasty. This is related to the obstructive effects of introducer sheaths in small diameter, immature AAVA's and venospasm induced by introducer sheath removal. The DAVQ measurements in the Maimonides series were made within 2 weeks of the procedure. Presumably any procedure-induced vasospasm would have completely abated by the time these measurements were taken.

In immature AAVA's the size of the introducer is often large relative to the size of the access so that the introducer itself becomes a significant obstruction to flow. This is an obvious point to the experienced interventionalist. It becomes even more readily apparent when these relationships are visualized in real time with ultrasound.

In the immediate post introducer removal state there is often spasm visualized at the introducer site. This is more often the case with retrograde introducers placed in the

**Table 5** Clinical reports of duplex-guided AV access intervention.

Year	Author	Location	n <sup>a</sup>	Technical success	VF <sup>b</sup> Pre PTA (mL/min)	VF Post PTA (mL/min)	P	% Increase in VF <sup>c</sup>	Clinical endpoint
2010	Fox	New York	223	219/223	340 (12–3265)	663 (116–4475)	<.001	95%	—
2009	Ascher	New York	32	32/32	350 ± 180	933 ± 332	<.0001	—	1, 3 and 6-month primary cumulative stenosis-free patency rates: 96% 76% & 53%
2009	Wang	Philadelphia	Case report	1/1	—	—	—	—	—
2007	Ascher	New York	11	11/11	614 ± 339	1103 ± 416	<.01	118 ± 100%	100% 3-month stenosis-free patency
2007	Marks	New York	10	10/10	658 ± 324	1154 ± 402	<.01	107 ± 97%	100% 3-month stenosis-free patency
2007	Kim	Daejeon, Korea	10	10/10	167 (80–259)	394 (120–586)	—	—	One or more successful hemodialysis sessions after treatment
2000	Bacchini	Lecco, Italy	12	12/12	468 ± 153	820 ± 281	<.001	—	100% patent at one month
1996	Wittenberg	Wurzburg, Germany	39	38/39	361 ± 83.5	719 ± 189	—	—	—

<sup>a</sup> n, Number of interventions.<sup>b</sup> VF, Volume flow.<sup>c</sup> When reported.

venous or outflow side of an AAVA. Conversely, the ante-grade/arterial end introducers are less often associated with spasm, presumably related to higher pressures in this area. When we have observed these accesses for brief periods of time after introducer removal (less than an hour) we have consistently observed a decrease in spasm and a concomitant increase in volume flow.

Ultrasound-guided dialysis access intervention is not a new concept. It was first reported in 1991 by Cluley in a canine model of femoral arteriovenous access.<sup>8</sup> The first clinical report was by Wittenberg in 1996.<sup>17</sup> Subsequently, several other centers have published retrospective series and case reports (Table 5).<sup>1–7,10,11,16,17</sup> Our experience is the largest reported to date. Technical success overall appears to be excellent and is consistent across the reported series. The principle technical endpoint reported is an increase in volume flow, which was reported in all series. The most robust clinical endpoint analysis is from Ascher who reported 1, 3 and 6-month primary cumulative stenosis-free patency rates of 96, 76 and 53% respectively.<sup>1</sup> A limitation of their life-table analysis is that they did not distinguish mature from immature access. The majority of the angioplasties were performed on non-maturing AAVA's (27/32). This likely accounts for the low 6-month primary patency as a number of these AAVA's would have required repeat intervention to become functional. We saw a similar relative efficacy in our study as the volume flow following intervention in mature mal-functioning access was more pronounced than that seen after angioplasty of immature AAVA's. It is suggested that future studies look at mature and immature AAVA's separately in order to obtain a more accurate picture of technical and clinical efficacy in each of these rather different clinical circumstances.

Given the demonstrated benefits of ultrasound-guided access intervention, broader application is inevitable. Such applications include thrombectomy procedures, procedures utilizing trans-arterial access and treatment of inflow arterial stenosis.<sup>9,14,15</sup> We have had a small but developing experience with these interventions and anticipate that they will be the focus of future reports.

A deficiency of our study is the absence of an analysis of additional technical endpoints such as a quantitative change in diameter, flow velocity and a clinical endpoint, such as functional patency. A further limitation of our study is the absence of an analysis of the distribution of the anatomical sites of treated stenoses. An analysis of such factors was beyond the scale of this report but would ideally be included in future studies.

## Conclusion

Duplex-guided dialysis access intervention for maintenance and maturation can be performed safely and effectively in the office setting and is tolerated well by most patients. It offers the advantage of treating the patient without radiation or contrast. It also allows for accurate sizing of balloons and stents and assessment of the hemodynamic effects of intervention. It is suggested that this technique be considered as an important addition to the therapeutic armamentarium.

## Funding

None.

## Conflict of Interest

None.

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